



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

#333172 3433-333 KAG WEMMH/SB/08B (4/03)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449B/PTO
**INFORMATION DISCLOSURE
 STATEMENT BY APPLICANT**
(use as many sheets as necessary)

Sheet

1

of

1

Complete if Known

Application Number	10/025,282
Filing Date	December 19, 2001
First Named Inventor	Bleyer, M.
Group Art Unit	1632
Examiner Name	Nguyen, D

Attorney Docket Number

3433-333

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s) publisher city and/or country where published	T ²
ML		American National Standard, ANSI/AAMI 10993-1:1994. "Biological Evaluation of Medical Devices—Part 1: Guidance on Selection of Tests". Association for the Advancement of Medical Instrumentation. pp. 9-17.	
M		BALDRY, M.G.C., et al., "Disinfection with Peroxygen", <i>Industrial Biocides</i> , 1988. pp. 91-116, K. Payne, editor. John Wiley and Sons, Inc., New York.	
ML		BLOCK, S. "Peroxygen Compounds", <i>Disinfection, Sterilization and Preservation</i> , 5 th Edition 2001. pp. 185-204. Lippincott Williams & Wilkins, Philadelphia, PA.	
ML		DENTON, F.W., "Chlorhexidine", <i>Disinfection, Sterilization and Preservation</i> , S. Block, editor, 5 th Edition 2001. pp. 321-336. Lippincott Williams & Wilkins, Philadelphia, PA.	
ML		HORAK, D., et al. "Hydrogels in Endovascular Embolization. III. Radiopaque Spherical Particles, Their Preparation and Properties". <i>Biomaterials</i> , March 1987. Vol. 2, No. 8. pp. 142-145. Butterworth-Heinemann In Association With The Biological Engineering Society, England.	
ML		KROPP, B.P., et al. "Experimental Assessment of Small Intestinal Submucosa as a Bladder Wall Substitute". <i>Urology</i> , 1995. Vol. 46, No. 3. pp. 396-400. Elsevier Science, United States.	

Examiner Signature

luvia leavitt

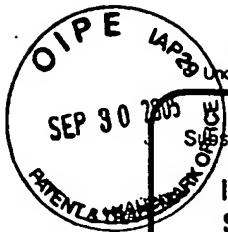
Date Considered

Oct 25 05

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

#333159 3433-333 KAG WEMMH/SB/08A (4/03)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet

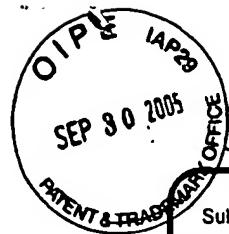
1 of 2

Complete if Known

Application Number	10/025,282
Filing Date	December 19, 2001
First Named Inventor	Bleyer, M.
Group Art Unit	1632
Examiner Name	Nguyen, D
Attorney Docket Number	3433-333

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number Number-Kind Code ³ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Application of Cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
ML		US-2,127,903	08/23/1938	Bowen, A.	
		US-3,562,820	02/16/1971	Braun, B.	
		US-4,795,741	01/03/1989	Leshchiner, et al.	
		US-4,902,508	02/20/1990	Badylak, et al.	
		US-4,956,178	09/11/1990	Badylak, et al.	
		US-5,139,505	08/18/1992	Palmieri, B.	
		US-5,141,747	05/25/1992	Scholz, M.	
		US-5,275,826	01/04/1994	Badylak, et al.	
		US-5,281,422	01/25/1994	Badylak, et al.	
		US-5,372,821	12/13/1994	Badylak, et al.	
		US-5,460,962	10/24/1995	Kemp, P.	
		US-5,554,389	09/10/1996	Badylak, et al.	
		US-5,601,602	02/11/1997	Fowler, B.	
		US-5,609,629	03/11/1997	Fearnott, et al.	
		US-5,676,146	10/14/1997	Scarborough, N.	
		US-5,676,689	10/14/1997	Kensey, et al.	
		US-5,749,894	05/12/1998	Engelson, E.	
		US-5,788,625	08/04/1998	Plouhar, et al.	
		US-5,885,619	03/23/1999	Patel, et al.	
		US-5,942,496	08/24/1999	Bonadio, et al.	
		US-5,997,575	12/07/1999	Whitson, et al.	
		US-5,997,895	12/07/1999	Tarotam, et al.	
		US-6,024,735	02/15/2000	Wolfinbarger, L.	
		US-6,042,605	03/28/2000	Martin, et al.	
		US-6,048,362	04/11/2000	Berg, T.	
		US-6,096,070	08/01/2000	Ragheb, et al.	
		US-6,099,567	08/08/2000	Badylak, et al.	
		US-6,206,931	03/27/2001	Cook, et al.	
		US-6,358,284	03/19/2002	Fearnott, et al.	
		US-6,475,232	11/05/2002	Babbs, et al.	
	↓	US 2002/0099448	07/25/2002	Hiles, et al.	
		US 2004/0078076	04/22/2004	Badylak, et al.	



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

633159 3433-333 KAG WEMMH/SB/08A (4/03)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet **2** of **2**

Complete if Known

Application Number **10/025,282**

Filing Date **December 19, 2001**

First Named Inventor **Bleyer, M.**

Group Art Unit **1632**

Examiner Name **Nguyen, D**

Attorney Docket Number **3433-333**

Examiner Initials ¹	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Application of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ²
		Country Code ³ -Number ² - Kind Code ⁴ (if known)				
ML		WO 94/26175	11/24/1994	Vitaphore Corporation		
ML		WO 95/22611	08/24/1995	The Regents of the University of Michigan		
ML		WO 96/24661	08/15/1996	Purdue Research Foundation, et al.		
ML		WO 96/25179	02/16/1996	Purdue Research Foundation		
ML		WO 96/32146	10/17/1996	Advanced Cytometric, Inc.		
ML		WO 97/19643	06/05/1997	Endomatrix, Inc.		
ML		WO 98/22158	05/28/1998	Cook Biotech, Inc., et al.		
ML		WO 98/25545	06/18/1998	Cook Biotech, Inc.		
ML		WO 98/25636	06/18/1998	Purdue Research Foundation		
ML		WO 98/25637	06/18/1998	Purdue Research Foundation		
ML		WO 98/26291	06/18/1998	Purdue Research Foundation		
ML		WO 99/44538	09/10/1999	The Regents of the University of California, et al.		

Examiner Signature	<i>luanice Neauith</i>	Date Considered	Oct 25 05
--------------------	------------------------	-----------------	-----------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). For Japanese patent documents, the indication of the year of the reign of the emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.